

**UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK**

SUSAN CHRISTENSEN,

Plaintiff,

vs.

MERCK & CO., INC. and NOVARTIS
PHARMACEUTICAL CORPORATION,

Defendants.

Civil Action No.: 1:07-cv-07053-JFK

**ANSWER AND DEFENSES OF
DEFENDANT NOVARTIS
PHARMACEUTICALS
CORPORATION TO PLAINTIFF'S
COMPLAINT**

JURY DEMAND

Defendant Novartis Pharmaceuticals Corporation ("NPC") responds to plaintiff's Complaint ("the Complaint") as follows:

With respect to the introductory paragraph preceding Paragraph 1 of the Complaint and the Caption, NPC denies that its name is Novartis Pharmaceutical Corporation and affirmatively avers that its name is Novartis Pharmaceuticals Corporation. The introductory paragraph preceding Paragraph 1 of the Complaint also contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the remaining allegations contained in the introductory paragraph preceding Paragraph 1 of the Complaint.

1. The allegations in the first sentence in Paragraph 1 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the first sentence in Paragraph 1 of the Complaint and therefore denies the same. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the second sentence in Paragraph 1 of the Complaint and therefore denies the same. The allegations

in the third sentence in Paragraph 1 of the Complaint contain allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the third sentence in Paragraph 1 of the Complaint and therefore denies the same. With respect to the fourth sentence in Paragraph 1 of the Complaint, NPC denies that it is a corporation incorporated under the laws of the state of New Jersey. NPC affirmatively avers that it is a corporation incorporated under the laws of the state of Delaware with its principal offices located in East Hanover, New Jersey. The allegations in the fifth sentence in Paragraph 1 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the fifth sentence in Paragraph 1 of the Complaint and therefore denies the same.

2. The allegations in Paragraph 2 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 2 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 2 of the Complaint. In particular, NPC denies the allegations in Paragraph 2 of the Complaint to the extent they relate to any claims asserted against NPC.

3. The allegations in Paragraph 3 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 3 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 3 of the Complaint as they relate to parties other than NPC and therefore

denies the same. NPC denies the remaining allegations in Paragraph 3 of the Complaint. NPC specifically denies that Aredia® and/or Zometa® caused any injuries alleged in the Complaint.

4. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 4 of the Complaint and therefore denies the same.

5. Paragraph 5 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 5 of the Complaint and therefore denies the same. NPC denies the remaining allegations in Paragraph 5 of the Complaint.

6. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts are “at all times herein mentioned” and therefore NPC is unable to respond to the allegations in Paragraph 6 of the Complaint. To the extent that a response is required, NPC admits that it is a corporation incorporated under the laws of the state of Delaware with its principal offices located in East Hanover, New Jersey.

7. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts are “at all times herein mentioned” and therefore NPC is unable to respond to the allegations in Paragraph 7 of the Complaint. Further, Paragraph 7 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits that it does business in the state of Utah. NPC denies the remaining allegations in Paragraph 7 of the Complaint.

8. Paragraph 8 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks

sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 8 of the Complaint and therefore denies the same.

9. Paragraph 9 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 9 of the Complaint and therefore denies the same.

10. Paragraph 10 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 10 of the Complaint and therefore denies the same.

11. Paragraph 11 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 11 of the Complaint and therefore denies the same.

12. Paragraph 12 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 12 of the Complaint and therefore denies the same.

13. Paragraph 13 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 13 of the Complaint and therefore denies the same.

14. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts are “[a]t all relevant times” and therefore NPC is unable to respond to the allegations in Paragraph 14 of the Complaint. To the extent that a response is required, NPC admits that it markets, advertises, distributes, and sells Zometa®, and that it sells and distributes Aredia®. NPC admits that in the past it did market and advertise Aredia®. NPC denies the remaining allegations in Paragraph 14 of the Complaint.

15. Paragraph 15 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 15 of the Complaint and therefore denies the same.

16. Paragraph 16 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 16 of the Complaint regarding parties other than NPC and therefore denies the same. NPC admits that Aredia® and Zometa® are bisphosphonic acids approved by the Food and Drug Administration (“FDA”) for the indications listed on each product’s label. NPC denies the allegations in Paragraph 16 of the Complaint to the extent that they mischaracterize or misstate information contained on the label for Aredia® and/or Zometa®. NPC also refers the Court to the prescribing information contained on the label for Fosamax® and/or other bisphosphonic acids unidentified in Paragraph 16 of the Complaint, and denies any allegations in Paragraph 16 of the Complaint to the extent that they mischaracterize or misstate that prescribing information. NPC denies any remaining allegations in Paragraph 16 of the Complaint.

17. In response to the first sentence in Paragraph 17 of the Complaint, NPC does not know the meaning plaintiff ascribes to the phrase "successor-drug", and, therefore is unable to respond to the allegations contained therein and denies the same. To the extent that a response is required, NPC denies the allegations in the first sentence in Paragraph 17 of the Complaint. The allegations in the second and third sentences in Paragraph 17 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations contained in the second and third sentences in Paragraph 17 of the Complaint.

18. Paragraph 18 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC admits only that some bisphosphonates contain nitrogen and some do not and that Aredia® is a bisphosphonic acid that contains the nitrogen atom. NPC refers the Court to the PDR for Fosamax® for its actual language and full text. NPC also refers the Court to the information contained on the labeling for Fosamax®, Aredia®, Boniva®, Actonel®, Didronel®, Bonefos®, Loron®, and Skelid®, and denies any allegations in Paragraph 18 of the Complaint to the extent that they mischaracterize or misstate that labeling information. NPC denies any remaining allegations in Paragraph 18 of the Complaint.

19. NPC denies the allegations in the first sentence in Paragraph 19 of the Complaint. To the extent that the allegations in the second sentence in Paragraph 19 of the Complaint relate to NPC, NPC denies the allegations contained therein. To the extent that the allegations in the second sentence in Paragraph 19 of the Complaint relate to parties other than NPC, no response is required. To the extent that a response is required, NPC denies all remaining allegations in Paragraph 19 of the Complaint.

20. To the extent that the allegations in Paragraph 20 of the Complaint relate to NPC, NPC denies the allegations contained therein. To the extent that the allegations in Paragraph 20 of the Complaint relate to parties other than NPC, no response is required. To the extent that a response is required, NPC denies all remaining allegations in Paragraph 20 of the Complaint.

21. To the extent that the allegations in Paragraph 21 of the Complaint relate to NPC, NPC denies the allegations contained therein. To the extent that the allegations in Paragraph 21 of the Complaint relate to parties other than NPC, no response is required. To the extent that a response is required, NPC denies all remaining allegations in Paragraph 21 of the Complaint.

22. Paragraph 22 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 22 of the Complaint and therefore denies the same.

23. NPC denies the allegations contained in Paragraph 23 of the Complaint.

24. Paragraph 24 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 24 of the Complaint regarding parties other than NPC and therefore denies the same. NPC denies all allegations in Paragraph 24 to the extent that they relate to NPC.

25. NPC denies the allegations contained in Paragraph 25 of the Complaint.

26. Paragraph 26 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 26 of the Complaint and therefore denies the same.

27. NPC admits that the FDA drafted an “ODS Postmarketing Safety Review,” dated August 25, 2004, but avers that the document speaks for itself. NPC denies the allegations in Paragraph 27 of the Complaint to the extent that they mischaracterize or misstate that document and/or its contents. NPC denies any remaining allegations in Paragraph 27 of the Complaint.

28. Paragraph 28 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 28 of the Complaint.

29. Paragraph 29 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 29 of the Complaint and therefore denies the same. NPC also refers the Court to the labeling for Fosamax®, and avers that the labeling speaks for itself.

30. In response to the allegations in the first clause in Paragraph 30 of the Complaint, NPC admits that changes to the labeling for Aredia® and Zometa® were made in 2003. The allegations in the second and third clauses in Paragraph 30 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations therein. NPC denies all remaining allegations in Paragraph 30 of the Complaint.

31. Paragraph 31 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 31 of the Complaint and therefore denies the same.

32. NPC admits that in 2004, Dr. Ruggiero and others published an article entitled "Osteonecrosis of the Jaws Associated with the Use of Bisphosphonates: A Review of 63 cases," in the Journal of Oral and Maxillofacial Surgery. NPC admits that the quoted language appears in this article, but avers that the article speaks for itself. NPC denies the remaining allegations in Paragraph 32 of the Complaint to the extent that they mischaracterize or misstate information contained in said article.

33. The allegations in Paragraph 33 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that it sent correspondence to medical professionals in September 2004 and May 2005 addressing the subject of osteonecrosis of the jaw. NPC denies the remaining allegations in Paragraph 33 of the Complaint.

34. Paragraph 34 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 34 of the Complaint and therefore denies the same.

35. Paragraph 35 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 35 of the Complaint and therefore denies the same.

36. Paragraph 36 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 36 of the Complaint and therefore denies the same.

37. The allegations in Paragraph 37 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 37 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 37 of the Complaint and therefore denies the same.

38. The allegations in the first sentence in Paragraph 38 of the Complaint constitute legal conclusions to which no response is required. Further, the first sentence in Paragraph 38 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the first sentence in Paragraph 38 of the Complaint and therefore denies the same. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the second sentence in Paragraph 38 of the Complaint and therefore denies the same.

39. The allegations in Paragraph 39 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 39 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 39 of the Complaint and therefore denies the same.

40. In response to Paragraph 40 of the Complaint, NPC admits that it tests, labels, markets, distributes, and sells Zometa®, and that it labels, sells, and distributes Aredia®. NPC admits that in the past it did test and market Aredia®. NPC denies the remaining allegations in Paragraph 40 of the Complaint.

41. In response to Paragraph 41 of the Complaint, NPC admits that Aredia® is a brand name under which NPC sells pamidronate disodium. NPC admits that Aredia® is a bisphosphonic acid. NPC admits that Aredia® is a prescription drug given intravenously to cancer patients. NPC denies all remaining allegations in Paragraph 41 of the Complaint.

42. NPC denies the allegations contained in Paragraph 42 of the Complaint. NPC affirmatively avers that Aredia® is approved by the Food and Drug Administration (“FDA”) for the indications listed on the product’s label.

43. NPC lacks sufficient knowledge or information to determine the meaning of the term “product literature” and what time periods plaintiff asserts in Paragraph 43 of the Complaint. Therefore, NPC is unable to respond to the allegations in Paragraph 43 of the Complaint. To the extent that a response is required, NPC denies the allegations in Paragraph 43 of the Complaint.

44. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 44 of the Complaint and therefore denies the same.

45. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 45 of the Complaint and therefore denies the same.

46. NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 46 of the Complaint and therefore denies the same.

47. The allegations in Paragraph 47 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 47 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 47 of the Complaint and therefore denies the same.

48. The allegations in Paragraph 48 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 48 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 48 of the Complaint.

49. The allegations in Paragraph 49 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 49 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 49 of the Complaint.

50. The allegations in Paragraph 50 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 50 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 50 of the Complaint and therefore denies the same.

51. The allegations in Paragraph 51 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 51 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 51 of the Complaint.

52. The allegations in Paragraph 52 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 52 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 52 of the Complaint and therefore denies the same.

53. The allegations in Paragraph 53 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 53 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 53 of the Complaint.

54. In response to Paragraph 54 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

55. The allegations in Paragraph 55 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 55 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 55 of the Complaint and therefore denies the same.

56. The allegations in Paragraph 56 of the Complaint and its subparts (a)-(f) constitute legal conclusions to which no response is required. Further, Paragraph 56 of the Complaint and its subparts (a)-(f) contain allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 56 of the Complaint and its subparts (a)-(f) and therefore denies the same.

57. The allegations in the first sentence in Paragraph 57 of the Complaint constitute legal conclusions to which no response is required. Further, the first sentence in Paragraph 57 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the first sentence in Paragraph 57 of the Complaint and therefore denies the same. NPC lacks sufficient knowledge or information

to form a belief as to the truth of the remaining allegations in Paragraph 57 of the Complaint and therefore denies the same.

58. The allegations in Paragraph 58 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 58 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 58 of the Complaint and therefore denies the same.

59. In response to Paragraph 59 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

60. The allegations in Paragraph 60 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 60 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 60 of the Complaint and therefore denies the same.

61. Paragraph 61 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 61 of the Complaint and therefore denies the same.

62. Paragraph 62 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 62 of the Complaint and therefore denies the same.

63. The allegations in Paragraph 63 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 63 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 63 of the Complaint and therefore denies the same.

64. The allegations in Paragraph 64 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 64 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 64 of the Complaint and therefore denies the same.

65. The allegations in Paragraph 65 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 65 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 65 of the Complaint and therefore denies the same.

66. The allegations in Paragraph 66 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 66 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 66 of the Complaint and therefore denies the same.

67. The allegations in Paragraph 67 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 67 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response

is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 67 of the Complaint and therefore denies the same.

68. The allegations in Paragraph 68 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 68 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 68 of the Complaint and therefore denies the same.

69. The allegations in the first sentence in Paragraph 69 of the Complaint constitute legal conclusions to which no response is required. Further, the first sentence in Paragraph 69 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the first sentence in Paragraph 69 of the Complaint and therefore denies the same. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 69 of the Complaint and therefore denies the same.

70. The allegations in Paragraph 70 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 70 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 70 of the Complaint and therefore denies the same.

71. In response to Paragraph 71 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

72. Paragraph 72 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 72 of the Complaint and therefore denies the same.

73. The allegations in Paragraph 73 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 73 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 73 of the Complaint and therefore denies the same.

74. The allegations in Paragraph 74 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 74 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 74 of the Complaint and therefore denies the same.

75. Paragraph 75 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 75 of the Complaint and therefore denies the same.

76. The allegations in the first sentence in Paragraph 76 of the Complaint constitute legal conclusions to which no response is required. Further, the first sentence in Paragraph 76 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the first sentence in Paragraph 76

of the Complaint and therefore denies the same. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 76 of the Complaint and therefore denies the same.

77. The allegations in Paragraph 77 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 77 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 77 of the Complaint and therefore denies the same.

78. In response to Paragraph 78 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

79. Paragraph 79 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 79 of the Complaint and therefore denies the same.

80. Paragraph 80 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 80 of the Complaint and therefore denies the same.

81. Paragraph 81 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 81 of the Complaint and therefore denies the same.

82. Paragraph 82 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 82 of the Complaint and therefore denies the same.

83. The allegations in Paragraph 83 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 83 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 83 of the Complaint and therefore denies the same.

84. Paragraph 84 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 84 of the Complaint and therefore denies the same.

85. Paragraph 85 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 85 of the Complaint and therefore denies the same.

86. The allegations in the first sentence in Paragraph 86 of the Complaint constitute legal conclusions to which no response is required. Further, the first sentence in Paragraph 86 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the first sentence in Paragraph 86 of the Complaint and therefore denies the same. NPC lacks sufficient knowledge or information

to form a belief as to the truth of the remaining allegations in Paragraph 86 of the Complaint and therefore denies the same.

87. The allegations in Paragraph 87 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 87 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 87 of the Complaint and therefore denies the same.

88. In response to Paragraph 88 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

89. The allegations in Paragraph 89 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 89 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 89 of the Complaint and therefore denies the same.

90. The allegations in Paragraph 90 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 90 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 90 of the Complaint and therefore denies the same.

91. Paragraph 91 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 91 of the Complaint and therefore denies the same.

92. Paragraph 92 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 92 of the Complaint and therefore denies the same.

93. Paragraph 93 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 93 of the Complaint and therefore denies the same.

94. The allegations in Paragraph 94 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 94 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 94 of the Complaint and therefore denies the same.

95. The allegations in the first sentence in Paragraph 95 of the Complaint constitute legal conclusions to which no response is required. Further, the first sentence in Paragraph 95 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in the first sentence in Paragraph 95 of the Complaint and therefore denies the same. NPC lacks sufficient knowledge or information to form a belief as to the truth of the remaining allegations in Paragraph 95 of the Complaint and therefore denies the same.

96. The allegations in Paragraph 96 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 96 of the Complaint contains allegations

regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 96 of the Complaint and therefore denies the same.

97. In response to Paragraph 97 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

98. The allegations in Paragraph 98 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 98 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 98 of the Complaint and therefore denies the same.

99. Paragraph 99 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 99 of the Complaint and therefore denies the same.

100. Paragraph 100 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 100 of the Complaint and therefore denies the same.

101. Paragraph 101 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 101 of the Complaint and therefore denies the same.

102. Paragraph 102 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 102 of the Complaint and therefore denies the same.

103. The allegations in Paragraph 103 of the Complaint constitute legal conclusions to which no response is required. Further, Paragraph 103 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 103 of the Complaint and therefore denies the same.

104. In response to Paragraph 104 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

105. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 105 and therefore is unable to respond to the allegations asserted therein. NPC admits that it labels, sells, and distributes Aredia®. NPC admits that in the past it did test and market Aredia®. NPC denies the remaining allegations in Paragraph 105 of the Complaint.

106. The allegations in Paragraph 106 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 106 of the Complaint. NPC specifically denies that Aredia® is “defective” or “unreasonably dangerous.”

107. The allegations in Paragraph 107 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in

Paragraph 107 of the Complaint. NPC specifically denies that Aredia® is “defective” or “unreasonably dangerous.”

108. The allegations in Paragraph 108 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 108 of the Complaint. NPC specifically denies that Aredia® is “defective.”

109. The allegations in Paragraph 109 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 109 of the Complaint. NPC specifically denies that Aredia® is “defective.”

110. NPC lacks sufficient knowledge or information to determine whether plaintiff was injured and is therefore unable to respond to the allegations in Paragraph 110 of the Complaint and denies the same. NPC admits that it sells Aredia®. The remaining allegations in Paragraph 110 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 110 of the Complaint.

111. In response to Paragraph 111 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

112. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 112 and therefore is unable to respond to the allegations asserted therein. NPC admits that it labels, sells, and distributes Aredia®. NPC admits that in the past it did test and market Aredia®. NPC denies the remaining allegations in Paragraph 112 of the Complaint.

113. The allegations in Paragraph 113 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 113 of the Complaint.

114. The allegations in Paragraph 114 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 114 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Aredia®.

115. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore NPC is unable to respond to the allegations in Paragraph 115 of the Complaint and denies the same. The remaining allegations in Paragraph 115 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 115 of the Complaint.

116. In response to Paragraph 116 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

117. NPC lacks sufficient knowledge or information to determine what time periods plaintiff asserts in Paragraph 117 and therefore is unable to respond to the allegations asserted therein. NPC admits that it labels, sells, and distributes Aredia®. NPC admits that in the past it did test and market Aredia®. NPC denies the remaining allegations in Paragraph 117 of the Complaint.

118. The allegations in Paragraph 118 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC admits that applicable law imposes certain duties upon manufacturers and distributors of products, but denies that Paragraph 118 accurately sets forth those duties. NPC denies the remaining allegations in Paragraph 118.

119. The allegations in Paragraph 119 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 119 of the Complaint.

120. The allegations in Paragraph 120 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 120 of the Complaint.

121. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore NPC is unable to respond to the allegations in Paragraph 121 of the Complaint and denies the same. The remaining allegations in Paragraph 121 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 121.

122. In response to Paragraph 122 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

123. The allegations in Paragraph 123 of the Complaint constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 123 of the Complaint.

124. The allegations in Paragraph 124 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 124 of the Complaint and therefore denies the same.

125. The allegations in Paragraph 125 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in

Paragraph 125 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Aredia®.

126. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore NPC is unable to respond to the allegations in Paragraph 126 of the Complaint and denies the same. The remaining allegations in Paragraph 126 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 126 of the Complaint.

127. In response to Paragraph 127 of the Complaint, NPC incorporates by reference its responses to the allegations in all preceding paragraphs of the Complaint.

128. The allegations in Paragraph 128 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 128 of the Complaint.

129. The allegations in Paragraph 129 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC lacks sufficient knowledge or information to form a belief as to the truth of the allegations in Paragraph 129 of the Complaint and therefore denies the same.

130. The allegations in Paragraph 130 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 130 of the Complaint. NPC specifically denies that any injuries alleged in the Complaint were caused by Aredia®.

131. NPC lacks sufficient knowledge or information to determine whether plaintiff suffered any injury and therefore NPC is unable to respond to the allegations in Paragraph 131 of the Complaint and denies the same. The remaining allegations in Paragraph 131 constitute legal

conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 131 of the Complaint.

132. The allegations in Paragraph 132 constitute legal conclusions to which no response is required. To the extent that a response is required, NPC denies the allegations in Paragraph 132 of the Complaint. NPC specifically denies that plaintiff is entitled to any of the relief sought in Paragraph 132 of the Complaint. In particular, NPC denies that plaintiff is entitled to punitive damages.

133. With respect to the allegations of the unnumbered paragraph and its subparts (a) through (e) following Paragraph 132, which begin with the word "WHEREFORE," these allegations constitute legal conclusions to which no response is required. Further, Paragraph 132 of the Complaint contains allegations regarding parties other than NPC to which no response is required. To the extent that a response is required, NPC denies that plaintiff is entitled to any of the relief requested in the unnumbered paragraph and its subparts (a) through (e) following Paragraph 132.

134. Every allegation in the Complaint that is not specifically and expressly admitted in this Answer is hereby specifically and expressly denied.

AFFIRMATIVE DEFENSES

1. The Complaint, in whole or part, fails to state a claim or cause of action against NPC upon which relief can be granted.

2. All claims against defendants other than Novartis Pharmaceuticals Corporation are improperly joined or fraudulently joined in this action.

3. Venue is inconvenient to the parties in the United States District Court for the Southern District of New York, and this matter should be transferred to an appropriate jurisdiction.

4. The doctrines contained in Restatement (Second) of Torts § 402A, Comment K, bar plaintiff's claims against NPC in whole or in part.

5. The doctrine(s) contained in Restatement (Third) of Torts, Product Liability §§ 4 and 6, bar plaintiff's claims against NPC in whole or in part.

6. Applicable statutes of limitations or repose bar plaintiff's claims in whole or in part.

7. Plaintiff's misuse or abnormal use of the products or failure to follow instructions bar the plaintiff's claims in whole or in part.

8. The alleged injuries to plaintiff were proximately caused by the misuse, abuse, alteration, and/or failure to properly utilize, maintain, or care for the products by persons other than NPC.

9. If plaintiff used a product sold by NPC, then plaintiff's claims are barred, in whole or in part, because plaintiff assumed the risks disclosed by the product labeling, by the prescribing physicians, or by other persons or entities.

10. Any alleged negligent or culpable conduct of NPC, none being admitted, was so insubstantial as to be insufficient to be a proximate or substantial contributing cause of plaintiff's alleged injuries.

11. If plaintiff used a product sold by NPC, plaintiff used the product for "off-label" purposes, which bars the plaintiff's claims.

12. The "learned intermediary" doctrine bars plaintiff's claims.

13. Plaintiff's claims are barred, in whole or in part, because the products at issue were designed, manufactured, marketed and labeled with proper warnings, information, cautions and instructions, in accordance with the state of the art and the state of scientific and technological knowledge.

14. Plaintiff's claims are barred, in whole or in part, because the labels and information accompanying the products at issue were approved by the U.S. Food and Drug Administration or other appropriate regulatory agencies.

15. Plaintiff's claims are barred, in whole or in part, by applicable products liability statutes or other law providing absolute or limited immunity or a disputable presumption of immunity against liability for pharmaceutical products approved by the FDA.

16. Plaintiff's claims are barred, in whole or in part, because the products at issue were not defective or unreasonably dangerous in that they complied with, at all relevant times, all applicable government safety standards.

17. Plaintiff's claims are preempted, in whole or in part, by applicable federal law relating to the design, testing, producing, manufacturing, labeling, distributing, modeling, processing, and supply of Aredia® and/or Zometa®.

18. Plaintiff's claims are barred, in whole or in part, because plaintiff's injuries, if any, were the result of conduct of plaintiff, independent third parties, and/or events that were extraordinary under the circumstances, not foreseeable in the normal course of events, and/or independent, intervening and superseding causes of the alleged injuries, including but not limited to plaintiff's pre-existing medical conditions.

19. If plaintiff suffered injury or damages as alleged, which is denied, such injury or damage resulted from acts or omissions of persons or entities for which NPC is neither liable nor responsible or resulted from diseases and/or causes that are not related to or connected with any product sold, distributed, or manufactured by NPC. Such acts or omissions on the part of others or diseases or causes constitute an independent, intervening and sole proximate cause of plaintiff's alleged injury or damages.

20. Plaintiff's claims are barred, in whole or in part, because plaintiff's alleged injuries, if caused by Aredia® and/or Zometa®, which is denied, were the result of plaintiff's own idiosyncratic reactions.

21. Plaintiff failed to mitigate, which limits plaintiff's damages, if any, in whole or in part.

22. Aredia® and/or Zometa® were fit and proper for their intended purposes and the social utility of the drugs outweighed any possible risk inherent in the use of the products.

23. NPC has no legal relationship or privity with plaintiff and owes no duty to plaintiff by which liability could be attributed to it.

24. The claims of plaintiff should be diminished in whole or in part in the amount paid to plaintiff by any party or non-party with whom plaintiff has settled or may settle.

25. Plaintiff's claims are barred, reduced and/or limited pursuant to applicable statutory and common law regarding limitations of awards, caps on recovery, and setoffs.

26. NPC made no warranties of any kind, express or implied, or any representations of any nature whatsoever to plaintiff. If any such warranties were made, whether express or

implied, which NPC specifically denies, then plaintiff did not rely on any such representations or warranties and/or failed to give notice of any breach thereof.

27. Notwithstanding the claims and contentions of plaintiff, plaintiff received all or substantially all of the benefit from the products that plaintiff hoped and intended to receive, and, to that extent, any damages and/or restitution that plaintiff might be entitled to recover from NPC must be correspondingly reduced.

28. Plaintiff's causes of action are barred in whole or in part by plaintiff's own contributory/comparative negligence.

29. Plaintiff's recovery, if any, shall be reduced by those payments that plaintiff receives from collateral sources.

30. If plaintiff has been injured or damaged, no injury or damages being admitted, such injuries were not caused by an NPC product.

31. Plaintiff's claims for punitive damages are barred because such an award would violate NPC's due process, equal protection and/or other rights under the United States Constitution, the New Jersey Constitution, the Utah Constitution, the New York Constitution, and/or other applicable state constitutions.

32. Plaintiff's claims for punitive damages are barred because plaintiff has failed to allege conduct warranting imposition of punitive damages under New Jersey, Utah, New York and/or other applicable state laws.

33. Plaintiff's claim for punitive damages is preempted, in whole or in part, by applicable federal law.

34. To the extent that New Jersey law applies to plaintiff's claims, plaintiff is limited in the amount, if any, she may recover for punitive damages under N.J.S.T. § 2A:15-5.9 *et seq.*

35. To the extent that New Jersey law applies to plaintiff's claims, plaintiff is barred from recovering punitive damages under N.J.S.T. § 2A:58C-5(c) because Zometa® and Aredia® were subject to pre-market approval by the FDA, were approved by the FDA, and/or were generally recognized as safe and effective pursuant to regulations and conditions established by the FDA.

36. Punitive damages against NPC cannot be recovered based on alleged fraudulent representation to the FDA. *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 343 (2001); *see also* N.J.S.T. § 2A:58C-5(c).

37. Plaintiff's claims for punitive damages are barred in whole or in part because plaintiff is not entitled to compensatory damages, no fault or other admissions being made.

38. Any liability that might otherwise be imposed upon NPC is subject to reduction by the application of the doctrine of comparative fault and/or negligence and/or contributory negligence, no fault, negligence, or other admissions being made.

39. NPC is not jointly and severally liable for any damages recoverable to the extent that such damages result from the conduct of parties other than NPC, no fault, damages, or other admissions being made.

40. NPC hereby gives notice that it intends to rely upon such other defenses as may become available or apparent during the course of discovery and thus reserves its right to amend this Answer to assert such defenses.

WHEREFORE, Defendant NPC demands judgment in its favor and against plaintiff, dismissing plaintiff's Complaint with prejudice, together with the costs of suit and such other relief as the Court deems equitable and just.

JURY DEMAND

Defendant Novartis Pharmaceuticals Corporation demands a jury trial as to all issues so triable.

Dated: September 10, 2007

Respectfully submitted,

s/ Ethan D. Stein
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CERTIFICATE OF SERVICE

I hereby certify that on September 10, 2007, the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiff's Complaint was filed with the Clerk of the Court and served in accordance with the Southern District's Rules on Electronic Service upon the following parties and participants:

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I further certify that on September 10, 2007, I served a true and correct copy of the Answer and Defenses of Defendant Novartis Pharmaceuticals Corporation to Plaintiff's Complaint, by United States Mail, postage prepaid, on:

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s/ Ethan D. Stein
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